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510(k) Summary of Safety and Effectiveness Information

NOV 2 7 2012

Date prepared: November 2, 2012

Submitted by:
Merete Medical GmbH
Alt Lankwitz 102
12247 Berlin, Germany

FDA Registration Number: 3002949614

Contact Person:
Donna Coleman
Merete Medical, Inc.
4 Crotty Lane – Suite 118
New York International Plaza
New Windsor, NY 12553
Phone. 914 967 1532

510(k) No.: K120787

Device Name: Merete Locking Bone Plate System III

Device Classification:
21 CRF 888.3030 Single/multiple component metallic bone fixation appliances and accessories (Plate, Fixation, Bone)
21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener (Screw, Fixation, Bone; Pin, Fixation, Smooth)

Product Codes:
HRS
HWC
HTY

Regulatory Class: Class II

Predicate Devices:
- Merete MetaFix™ Small Fragment Locking Bone Plate System – K050457
- Merete Locking Bone Plate System – K090063
- Merete 3.0 and 3.5 mm Locking Screws – K081513
- Ascension Total Plate System – K100502
- SBI K-Wires – K051605
- Kirschner and Guide Wires – K100736

Device Description:
The Merete Locking Bone Plate System III consists of contoured, anatomically shaped locking bone plates in various sizes and different curvatures for the fixation with Merete 3.0 and 3.5 mm locking screws and 3.0 mm cannulated compression screws. Before placing the screws, plates can be fixed temporarily with K-Wires.
Plates, screws and K-Wires of the Merete Locking Bone Plate System III are made of Ti-6Al-4V ELI Alloy for Surgical Implant Applications (ASTM F136, ISO 5832-3). K-Wires are additionally made of CrNiMo Stainless Steel for Surgical Implants (ASTM F138, ISO 5832-1).

Intended use:
The Merete Locking Bone Plate System III can be used for adult and pediatric patients.
Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes.

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Technological Characteristics:
The components of Merete Locking Bone Plate System III are similar to legally marketed predicate devices listed above in that they share similar indications of use, are manufactured from similar materials and incorporate similar technological characteristics.

Potential risks:
The risks associated with this device are the same as with any metallic internal fixation device. These include but not limited to the following: Delayed or nonunion which may lead to breakage of the implant. Bending or fracture of the implant, metal sensitivity, or allergic reaction to a foreign body. Pain, discomfort, or abnormal sensation due to the presence of the device.

Mechanical testing:
In order to demonstrate that the Merete Locking Bone Plate System III has the mechanical properties necessary to perform its intended use and that the device performs as well as or better than the predicate devices, Merete has conducted nonclinical mechanical testing. This includes:

- Dynamic 4-point bending fatigue test (per ASTM F382-2003 and ISO 9585)
- Screw torsion test (per ASTM F543 and ISO 6475)
- Engineering rationale

All tests considered the worst case scenario for the strength of the system and were passed successfully.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 27, 2012

Merete Medical GmbH
% Merete Medical, Incorporated
Ms. Donna Coleman
4 Crotty Lane – Suite 118
New York International Plaza
New Windsor, New York 12553

Re: K120787
Trade/Device Name: Merete Locking Bone Plate System III
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HTY
Dated: September 25, 2012
Received: October 1, 2012

Dear Ms. Coleman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

Indications for Use

510(k) Number (if known): K120781

Device Name: Merete Locking Bone Plate System III

Indications for Use:
The Merete Locking Bone Plate System

can be used for adult and pediatric patients. Indications for use include fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, feet, wrist, ankles, fingers, and toes.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi
for (Division Sign-Off)
Division of Orthopedic Devices

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